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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,556	11/16/2001	Jordan U. Gutterman	CLFR:009US/10111753	5224

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EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
04/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aopatent@fulbright.com

Office Action Summary	Application No.	Applicant(s)	
	09/992,556	GUTTERMAN ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9,10,22-32,41,44-52 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,10,22-32,41,44-52 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2009 has been entered.

Applicants' arguments, filed 12/14/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112--NEW

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9, 10, 22-32, 39, 41, 44-52 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the formula further comprises R4" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103--previous

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 2, 9, 10, 22-32, 39, 41 and 44-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable Arntzen et al., (US 6,444,233) and further in view of Ni et al., (US 5,965,421). This rejection also applies to newly added **claim 56**.

Arntzen et al., teaches novel saponin mixtures and compounds of a triterpene comprising the monoterpene moiety of the instant claim 1 (see col. 3, lines 1-17; see

also col. 6, 8-20 and figures 24, 36-41). The compounds are potent inhibitors of transcription factor NF-kB, which plays an important role in the inflammatory response (see col. 69, lines 54-65). The compounds are taught to be administered parenterally through injection, including directly into a disease site, orally, or topically and may also be administered in pharmaceutical form suitable for injection in sterile aqueous solutions containing oil, as per claims 51 and 52 (see col. 50, lines 58-62, col. 51, lines 12-16 and col. 52, lines 8-11 and 21-26). The reference teaches how the compounds inhibit induction of iNOS (see col.15, lines 40-42). The composition would be expected to inhibit COX-2 since, iNOS and COX-2 are both mediators of inflammation, sharing the similarities in mechanism of expression, as is well known[1]. Arntzen "contemplates a method of treating a mammal for inflammation, comprising administering to the mammal a therapeutically effective amount of the nutraceutical compositions described above" (see col. 6, lines 3-6).

Arntzen et al. differs from the instant claim insofar as it does not teach that the mammal has rheumatoid arthritis or inflammatory bowel disease.

Ni et al. teaches that disregulation of NF-kB activation has been linked to disorders such as rheumatoid arthritis and inflammatory bowel disease, and that "inhibitors of NF-kB could be used to treat these disorders" (see col. 16, lines 5-12).

Ni et al. does not teach the monoterpene of claim 1.

It would have been obvious to a person having ordinary skill in the art to have used the compounds of Arntzen to inhibiting inflammation in a subject having

[1] See Kun (US 5,908,861), at col. 19, lines 52-65.

rheumatoid arthritis or inflammatory bowel disease, since the compounds of Arntzen are useful for treating inflammation in mammals generally. Furthermore, since the compounds of Arntzen are potent inhibitors of NF-kB, it would have been obvious to use them in a method for treating rheumatoid arthritis or inflammatory bowel in a subject since these disorders can be treated using NF-kB inhibitors, as taught by Ni et al.

2) Claims 1, 2, 9, 10, 24-28, 31-32, 41, and 44-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable Arntzen et al., (WO 1999/59578) and further in view of Ni et al., (US 5,965,421). This rejection also applies to newly added **claim 56**.

Nonstatutory Obvious-type Double Patenting--previous

Claims 1, 2, 9, 10, 22-32, 39, 41, 46 and 48-51 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 16-21 of U.S. Patent No. 6,962,720. This rejection also applies to newly added **claim 56**.

Applicant argues that the above claims are not obvious over the claims of the '720 patent since the '720 patent does not mention rheumatoid arthritis or inflammatory bowel disease. However, the instant claims are not limited to a specific type of inflammation. It would have been obvious to a person having ordinary skill in the art to treat inflammation in a patient with rheumatoid arthritis or inflammatory bowel disease since these patients are expected to have inflammation. Furthermore, it is noted that

diseases such as rheumatoid arthritis or inflammatory bowel diseases are well known inflammatory diseases.[2]

Response to Arguments/Declaration

Applicant argues that dysregulation of NF-kB does not provide a reasonable basis for using an inhibitor of NF-kB for treating rheumatoid arthritis or inflammatory bowel disease, since dysregulation "may mean increased or decreased NF-kB activation." However, Ni specifically recites, in regard to rheumatoid arthritis and inflammatory bowel disease, "inhibitors of NF-kB could be used to treat these disorders." Thus, the reference is clear in regard to the type of NF-kB dysregulation, i.e. inhibition.

A declaration by Roger S. Anderson has also been submitted. The affiant discusses data where Avicin D is administered to an inflammatory bowel murine model. The mice were administered a 0.25 and 0.5 mg/kg subcutaneous dose of Avicin D. Histological findings showed lower medial disease severity, i.e. lesions of the colon, as compared to the positive control. However, affiant made no conclusions of unexpected results, reasons for why these data overcomes the 103 rejection, or how these results relate to rheumatoid arthritis. It is noted that these data are not unexpected insofar as Arntzen teaches that the compounds are useful for treating lesions in the colon (see col. 54, lines 6-8).

[2] See Ni. et al., (US 5,965,421) at col. 16, lines 5-12.

It is also noted that these data are not supported in the disclosure, nor are they commensurate in scope with the instant claims. The instant claims are drawn to "inhibiting inflammation in a subject", while these data show decrease in severe lesions of the colon. In other words, the instant claims are not necessarily drawn to treating inflammatory bowel lesions, but inflammation generally. Furthermore, the instant claims are much broader in scope insofar as they include a different patient population, i.e. rheumatoid arthritis, and support many treatment options in regard to dosage and route of administration. Accordingly, the instant claims remain rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb

/Walter E Webb/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612